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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
LUONG, PETER

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,222	BAMBOT ET AL.	
	Examiner	Art Unit	
	Peter Luong	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-63 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 August 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/09/2003 and 02/05/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 9/09/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities:

Page 7, line 17 – "the imaging device 7S" should be --the imaging device 78--.

Page 19, line 13 – "In fact, it some embodiments" should be --In fact, in some embodiments--.

Page 22, line 12 – "measurement in dominated" should be --measurement is dominated".

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 39 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15 and 17 of copending Application No. 11/601904. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim substantially the same subject matter to a method of detecting tissue characteristics comprising dividing an area of target tissue into a plurality of detection points arranged in columns, illuminating the plurality of detection points one column at a time, performing

spectroscopic measurements on optical energy received from the target tissue, and determining tissue characteristics of the target tissue based on the results of the spectroscopic measurements, wherein the plurality of detection points are illuminated using a probe positioned a predetermined distance from the target tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22, 56, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 22, as currently phrased, can be interpreted in a manner that would render the claim limitations unclear, i.e. "the spectrograph that reimages the collected optical energy prior to the collected optical energy entering the spectrograph". The examiner suggests the claim be amended as follows: --the collection filter wheel and the spectrograph; wherein the reimaging device reimages the collected...--

Claim 56 recites the limitation "the tube" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 58 recites the limitation "the tube" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-11, 14-19, 24-29, 31-38, 47-53, 55-57, and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Fulghum (US 6,364,829).

The patent of Fulghum discloses **an apparatus for determining tissue characteristics** (abstract) **comprising a base unit** (figure 2a) **comprising illumination** (214), **detection** (220) **and control** (378) **sub-units, the illumination sub-unit providing illumination optical energy for illuminating a target tissue** (218) (column 6, lines 1-4) **and the detection sub-unit detecting tissue characteristics of a target tissue** (column 6, lines 4-10), **a separate tissue interface unit** (202) **and a pathway coupling the base unit and the tissue interface unit** (figure 2a), **and a docking unit** (figures 2a, 11a, and 12) **comprising an illumination source** (316) **and a processor** (208).

With respect to claims 2-7, 24, 27, and 51, Fulghum discloses **the pathway comprises an illumination pathway** (200, 210, or 212) **and a collection pathway** (200, 220), **wherein the illumination pathway is configured to deliver optical energy from the base unit to the tissue interface unit and the collection pathway is configured to deliver collected optical energy reflected and/or emitted by a**

target tissue from the tissue interface unit to the base unit (column 5, lines 64-37 and column 6, lines 1-5. See also figures 2a and 2b).

With respect to claims 8-9, 25-26, 55, and 61, Fulghum discloses **an imaging device and an image pathway** (320) **configured to deliver image optical energy reflected off the target tissue to the imaging device, wherein the imaging device is a camera** (figure 3 and column 7, lines 13-16 and 41-43).

With respect to claims 10-11, 28-29, and 56-57, Fulghum discloses **the tissue interface unit comprises a base structure** (202)**, the tube being configured to be attachable to the base structure, wherein the base structure comprises a handle** (figure 2a).

With respect to claim 14, Fulghum discloses **the illumination sub-unit comprises an illumination source** (800) **and an illumination filter wheel** (818, see figure 3).

With respect to claim 15, Fulghum discloses **a cold mirror** (806) **coupled to the illumination source** (800) **and the illumination filter wheel** (818).

With respect to claim 16, Fulghum discloses **a lens** (804) **coupled to the illumination source** (800) **and the illumination filter wheel** (818).

With respect to claim 17, Fulghum discloses **a shutter** (808) **configured to selectively prevent illumination optical energy from entering the pathway that couples the base unit and the tissue interface unit** (figure 3).

With respect to claim 18 and 53, Fulghum discloses **the pathway that couples the base unit and the tissue interface unit is comprised of a plurality of optical fibers** (figure 3).

With respect to claim 19, Fulghum discloses **a mask** (808) **that provides for selective illumination of the target tissue.**

With respects to claims 31-38, the device of Fulghum would inherently be capable of performing the claimed method steps as the device of Fulghum has the structures to illuminate with multiple sources (316, 800), form images with multiple monitors (326, 384), and perform and determine spectroscopic measurements (334, 376). See MPEP 2112.

With respect to claim 47, the device of Fulghum would inherently support the tissue interface unit when placed on top of the device when not in use (see MPEP 2112).

With respect to claim 53, Fulghum discloses **a light guide** (312) **configured to deliver optical energy received from the docking unit to the target tissue via the tube and pathway** (figure 3).

With respect to claim 59, Fulghum discloses **a system interface** (322) **and controller** (378) **that controls the exchange of signals between the tissue interface unit and the docking unit** (figure 3).

With respect to claim 60, Fulghum discloses **a monitor** (326) **in communication with the imaging device** (figure 3).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 12-13, 20-23, 30, 54, 58, and 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulghum (US 6,364,829).

With respect to claims 12, 30, and 58, the patent of Fulghum discloses the subject matter substantially as claimed except for the tube being disposable.

However, it is old and well known to a person of ordinary skill in the art at the time the invention was made to dispose of the old tube as multiple uses would cause standard wear and tear to the tube.

With respect to claim 13, the patent of Fulghum discloses the subject matter substantially as claimed except for the base unit comprising a movable cart.

However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a movable cart to the device of Fulghum to make the device portable and movable, *In re Lindberg* (See MPEP 2144.04).

With respect to claims 20-23, 54, and 62-63, the patent of Fulghum discloses a spectrograph 334 (column 7, lines 50-53), a re-imaging device 332, and a camera (column 7, lines 41-43) (see figure 3).

The patent of Fulghum does not disclose a collection filter wheel and shutter in the detection sub-unit and a camera that receives optical energy from the spectrograph.

However, the patent of Fulghum does disclose the use of a filter wheel (318) and shutter (314) in the illuminating source. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the detection sub-unit of Fulghum with a filtering wheel (diffraction grating) and shutter and rearrange the camera to receive from the spectrograph as a duplication and rearrangement of parts is within the level of one of ordinary skill in the art, *In re Harza and In re Japikse* (See MPEP 2144.04).

13. Claims 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utzinger et al. (US 6,571,118).

The patent of Utzinger et al. discloses a method of illuminating a sample at a plurality of points (claim 44), performing spectroscopic measurements from the reflected optical energy (column 2, lines 24-30 and claim 44), and determining tissue characteristics of the tissue based on the measurements (column 4, lines 57-63).

However, the patent of Utzinger et al. does not explicitly disclose the method step of dividing the target tissue into a plurality of detection points arranged in columns and illuminating the columns one at a time.

The patent of Utzinger et al. does disclose the light passing through the objective may be focused to an appropriate shape to fill one or more fibers (column 8, lines 43-49). Figure 9A shows the fibers arranged in columns. As such, with the fibers arranged in columns, the target tissue would be divided into columns and illuminated in columns by focusing the objective lens. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method steps to illuminate the target tissue in columns in order to target specific areas of interest.

With respect to claims 40-41, Utzinger et al. discloses the methods can be applied to the cervix (column 4, lines 57-63).

With respect to claim 42, Utzinger et al. discloses a fiber that covers an area of 1 mm in diameter (column 27, line 61-62) and the probe consists of a total of 46 fibers (column 17, lines 13-14). Utzinger et al. does not disclose the detection area of approximately 25 mm in diameter. However, it would have been obvious to a person of

ordinary skill in the art at the time the invention was made to modify the size of the detection area to be approximately 25 mm in diameter by adding additional fibers in order to cover a larger area, *In Gardner v. TEC Systems, Inc.* (see MPEP 2144.04).

With respect to claim 43, Utzinger et al. discloses the fibers have a core diameter of 0.2 mm (column 10, lines 51-53). Utzinger et al. does not disclose the diameter of the detection points to be approximately 0.5 mm. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the optical fibers to be 0.5 mm in diameter in order to detect a larger area, *In Gardner v. TEC Systems, Inc.* (see MPEP 2144.04).

With respect to claim 44, Utzinger et al. discloses the fibers may be about 1.7 mm apart from each other (column 11, lines 4-6). Utzinger et al. does not disclose the detection points separated by approximately 3 mm apart from each other. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to rearrange the optical fibers to be 3 mm apart from each other in order to cover a larger area, *In Gardner v. TEC Systems, Inc.* (see MPEP 2144.04).

With respect to claim 45, Utzinger et al. discloses in figure 1 a probe (30) that is a predetermined distance from the target tissue (60).

With respect to claim 46, Utzinger et al. discloses the total probe length (the examiner takes the position that the total probe length includes the tube) to be about 28 cm to 35 cm (column 11, lines 7-9). Utzinger et al. does not disclose the probe positioned at a predetermined position of approximately 175 mm (17.5 cm) from the target tissue. However, it would have been obvious to a person of ordinary skill in the

art at the time the invention was made to modify the probe length of Utzinger et al. to approximately 175 mm (17.5 cm) as a change in size is within the level of one of ordinary skill in the art (see MPEP 2144.04).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patents of Hayashi, Jung et al., Kaneko et al., and Wang et al. all disclose fluorescence imaging devices for imaging tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571) 270-1609. The examiner can normally be reached on Monday - Thursday, 7:30 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on (571) 272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Terrence R. Till
Supervisory Patent Examiner

P.L.